Application No. 10/565,506

Amendment dated: September 18, 2009

## REMARKS

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have amended claims 3, 4, 5, 7-11, 13 and 19 as fully supported by the specification as originally filed. Applicants have canceled claims 1-2, 14-18 and 20 from the present application, without prejudice or disclaimer. Applicants submit that all of the claims now present in the application are fully supported by the specification as originally filed and are clearly patentable over the references of record.

The rejection of claims 1-3 and 5-20 under 35 U.S.C. 112, second paragraph, as indefinite has been carefully considered but is most respectfully traversed in view of the amendments to the claims. Claims 1 and 2 are cancelled herewith and claim 3 amended to remove the reference to preferable features. The Examiner's rejection on the basis of being indefinite under 35 U.S.C. 112 is thereby addressed and obviated.

The rejection of claims 14-16 and 20 under 35 U.S.C. 112, first paragraph, has been carefully considered but is most respectfully traversed in view of the amendments to the claims, canceling these claims without prejudice or disclaimer. While it is not believed that these claims lack enablement to one of ordinary skill in the art, with routine experimentation. The Examiner's rejection on the basis of lack of enablement under 35 U.S.C. 112 is therefore believed moot.

Claims 17 and 18 are cancelled herewith without prejudice or disclaimer. The Examiner's rejection on the basis of failing to recite process steps under 35 U.S.C. 112 is therefore believed moot.

The rejection of claims 1-4, 7-10 and 19 under 35 U.S.C. 102(b) as being anticipated by Vennerstrom et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims. The claim set is hereby limited to the compounds of claim 3, to methods of their synthesis and to corresponding pharmaceutical compositions. All compounds now claimed require an O-R<sub>3</sub> group at the center carbon. All compounds of Vannerstrom lack this group, having only an n-butyl, hydrogen and/or ethyl group at this position (Z=H or Et) in compounds 4 and 5. No compound having an oxygenated group at this position is disclosed in Vannerstrom.

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Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The Examiner's rejection on the basis of being anticipated by Vannerstrom under 35 U.S.C. 102 is thereby believed addressed and obviated.

The rejection of claims 1-4, 7-10 and 19 under 35 U.S.C. 103(a) as being unpatentable over Vennerstrom et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims. As now amended, all compounds are limited to those having an oxygenated group at the center carbon atom. Such compounds, both with and without the thiol  $T_1$  substituents, are demonstrated as highly effective in the suppression of cytokine production in Example 5 of the present application. The central  $OR_3$  group is believed to be important to this action and is therefore preserved in all compounds now claimed.

There is no teaching in Vennerstrom that would suggest activity of these compounds against cytokine production, specifically IL6 and GM-CSF as demonstrated in Figures 8 and 9. Neither are the oxygenated compounds disclosed in Vennerstrom nor are these cytokines discussed as potential targets. There is therefore considerable original research required to progress from Vennerstrom to the currently amended claims and thus the present active compounds cannot be obvious. It is acknowledged by the Examiner in Section 6, subsection (3) that compounds similar to the claimed malonamides are not widely known in the art and thus there is no reasonable

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expectation that these could be active in the way demonstrated. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 11-13 under 35 USC 103(a) as being unpatentable over Vennerstrom et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims. There is no teaching of the present oxygenated compounds of Vennerstrom. There is therefore no motivation to adapt the synthesis disclosed therein to the current structures. The skilled worker is not motivated by an expectation of anti-cytokine activity because this is shown for the first time in the present application. The methods of claims 11-13 are thus believed to be similarly nonobvious. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above amendments, an early action on the application is now in order and is most respectfully requested.

> Respectfully submitted, **BACON & THOMAS, PLLC**

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